



UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

TAKEDA CHEMICAL INDUSTRIES, LTD. and
TAKEDA PHARMACEUTICALS NORTH AMERICA,
INC.,

Plaintiffs,

- V -

MYLAN LABORATORIES, INC., MYLAN
PHARMACEUTICALS, INC., and UDL
LABORATORIES, INC.,

Defendants.

OPINION & ORDER

TAKEDA CHEMICAL INDUSTRIES, LTD. and
TAKEDA PHARMACEUTICALS NORTH AMERICA,
INC.,

Plaintiffs,

- V -

RANBAXY LABORATORIES, LTD., and RANBAXY
PHARMACEUTICALS, INC.,

Defendants.

03 CIV. 8250

TAKEDA CHEMICAL INDUSTRIES, LTD. and
TAKEDA PHARMACEUTICALS NORTH AMERICA,
INC

Plaintiffs

- 17 -

WATSON PHARMACEUTICALS, INC., WATSON
LABORATORIES, INC., WATSON PHARMA,
INC. and DANBURY PHARMACAL, INC..

Defendants -

03 CIV. 8254

TAKEDA CHEMICAL INDUSTRIES, LTD. and
TAKEDA PHARMACEUTICALS NORTH AMERICA,
INC.,

Plaintiffs,

- V -

04 CIV. 1966

ALPHAPHARM PTY. LTD. and GENPHARM,	:
INC.,	:
	:
Defendants.	:
-----X	

Appearances:

For Plaintiffs:

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For Defendants Mylan Laboratories,
Inc., Mylan Pharmaceuticals, Inc., and
UDL Laboratories, Inc.:

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DENISE COTE, District Judge:

Takeda Chemicals Industries, Ltd. and Takeda Pharmaceuticals North America, Inc. ("Takeda") have moved in limine to exclude substantial portions of the direct testimony from experts for Mylan Laboratories, Inc., Mylan Pharmaceuticals, Inc., and UDL Laboratories, Inc. ("Mylan"). Mylan has responded with its own cross-motions. The direct testimony for this bench trial was submitted in advance of trial through affidavits. This Opinion and Order addresses the motions as to Mylan experts Lawrence B. Hendry ("Hendry"), Martin Ronis ("Ronis"), and Mark E. Nusbaum ("Nusbaum"), and Takeda experts Bruce H. Stoner, Jr. ("Stoner") and Bernard R. Landau ("Landau").

Background

In 2003, Mylan sent Takeda a Notice of Paragraph IV Certification, in which it informed Takeda that it had submitted an Abbreviated New Drug application regarding the sale of Takeda's successful diabetes drug, pioglitazone, before the expiration of certain patents affecting the sale of pioglitazone. The notice asserted that Takeda's '777 patent, which protects the chemical compound for pioglitazone, was invalid on the basis of obviousness. Litigation ensued.

On April 25, 2005, with approximately one month to go before the conclusion of fact discovery, Mylan notified Takeda for the first time that it was now asserting that the '777 patent was unenforceable due to Takeda's lack of good faith and candor in applying for the patent.¹ See Takeda Pharmaceutical Industries, Ltd. v. Mylan Laboratories, Inc., 03 Civ. 8253 (DLC), 2005 WL 2092920, at *1 (S.D.N.Y. Aug. 31, 2005). At a conference on June 14, the Court ruled that Mylan could amend its answer to assert a claim of inequitable conduct.² Mylan was required, however, to

¹ By that time Mylan had abandoned its originally asserted claim of obviousness. In June 2005, Mylan tried unsuccessfully to assert a new claim of obviousness based on a newly identified reference. Takeda, 2005 WL 2092920, at *2.

² In ruling, the Court observed: "I don't want my granting the motion to amend to be taken as a finding that [Mylan was] sufficiently diligent or that the three items [Mylan has] identified would support a good faith claim of inequitable conduct. I'm ruling the way I'm ruling because of the extraordinary desire that issues, if at all possible be addressed on the merits in litigation. Litigation is important to all sides here, and if I can find a way to alleviate any prejudice that can be identified by the parties, I'll try to reach the merits where I can." Conference, June 14, 2005 at 54:7-15.

identify the bases for this newly minted claim either in its pleading or expert reports, which were required to be served on July 1. Takeda's responsive expert submissions were due September 2. The trial had long been scheduled to begin on January 17, 2006.

Ronis' deposition was taken on September 20, 2005. Hendry's deposition was taken on September 28, 2005. On November 18, the parties served the pretrial order, and the affidavits constituting the direct testimony of their witnesses, including their expert witnesses. Mylan did not submit any direct testimony from one of its experts on the inequitable conduct claim, Dr. Michael Rosenberg.³ Ronis' affidavit abandons many opinions which he had originally asserted in his July 1 expert report, and asserts many opinions that were not contained in that report. Some of the new material in Ronis' affidavit is material imported from other Mylan expert reports, including from Rosenberg's and Hendry's reports.

Ronis

Takeda's motion to strike from Ronis' affidavit those opinions that were not contained in his own July 1 report is granted. Similarly, to the extent that Ronis asserts new bases for opinions found in his July 1 report, those newly asserted bases for timely-asserted opinions must be stricken. Despite grave doubts as to Mylan's diligence, and concerns about the prejudice to Takeda, this Court allowed Mylan to assert an

³Takeda asserts, and Mylan has not disagreed, that Dr. Rosenberg was substantially discredited in his deposition.

inequitable conduct claim against Takeda near the close of fact discovery. Mylan had ample time to formulate carefully and thoroughly the bases for that claim as of the April 25 notice to Takeda and to articulate them accurately by the time it submitted its July 1 expert reports, and it does not argue otherwise.

Having failed to follow the Order of this Court at the June 14 conference, which required it to identify completely its theories supporting the inequitable conduct claim in the July 1 expert reports, Mylan shall not be permitted to prejudice Takeda further by improperly augmenting the direct testimony of its experts four and a half months later, and after the close of expert discovery.⁴

Mylan argues that much of the testimony that Takeda seeks to strike from Ronis' affidavit is a simple recitation of facts.⁵ Rule 26(a)(a)(2)(B) requires that an expert report "contain a complete statement of all opinions to be expressed and the basis and reasons therefor; the data or other information considered by the witness in forming the opinions" and "any exhibits to be used as a summary of or support for the opinions." Fed. R. Civ. P. 26. Mylan does not attempt to show how the "facts" to which it refers fall outside of these requirements. A review of the challenged portions of the Ronis affidavit indicates that the "facts" are simply a vehicle for the assertion of opinions (and

⁴Mylan has moved to exclude the supplemental declaration of Landau submitted by Takeda to respond to Ronis' new opinions. Mylan's desire to tender new material, but to prevent Takeda from addressing it, underscores why justice requires that Takeda's motion to strike new material in Ronis' affidavit be granted.

⁵Mylan admits that the Ronis affidavit "contains many factual details not found in his expert report."

the bases for opinions) that were not found in the July 1 report. It is telling in this regard that Mylan does not argue, much less attempt to show, that the facts that are the subject of Takeda's motion are simply evidentiary detail for the opinions expressed in Ronis' July 1 expert report. In the absence of such a showing, Takeda's motion is granted

Mylan argues that Ronis' summary of Takeda documents cannot surprise Takeda and that summaries are admissible under Rule 1006 of the Federal Rules of Evidence. Fed. R. Evid. 1006. Takeda was entitled to an appropriate expert disclosure on July 1, and its motion to strike is granted because of Mylan's failure in this regard, not because of a violation of Rule 1006. In any event, much of the evidentiary material, which is a summary of test data culled from Takeda notebooks reflecting scientific experiments, will be admitted through the affidavit of Mylan expert Hendry and does not relate to any admissible opinion expressed by Ronis.

Finally, Mylan contends that because Ronis' deposition touched upon much of the new material inserted into his affidavit, the motion should be denied. Discussion of a topic at a deposition is not a substitute for an expert report, at least where the deviations are as substantial as they are in this case. Without a timely produced expert report, served sufficiently in advance of a deposition so that the adversary can effectively use the services of its own expert to prepare for a deposition, the adversary does not have an adequate opportunity, at the deposition, to test the expert's opinions and qualifications to

assert those opinions.

Viewed against the backdrop of this entire litigation, Mylan's presentation of testimony through Ronis is the latest example of an assertion of new claims and theories as it loses confidence in its previous assertions. It is too late in the day to go through yet another iteration of claims.

Hendry

The thrust of Takeda's motion to strike portions of Hendry's affidavit is that much of the proffered direct testimony falls outside the area of Hendry's expertise. It is undisputed that Hendry is an expert in organic chemistry. Mylan seeks to have him recognized also as an expert in medicinal chemistry. It is unnecessary to decide whether Hendry is properly considered an expert in the field of medicinal chemistry as well, since many of the opinions he expresses, and analyses he undertakes in his affidavit to support those opinions, fall far outside the realm of medicinal chemistry. Takeda's motion is granted in part.

At his deposition, Hendry denied having any expertise in many areas of importance to the opinions he expresses and the material he discusses in his affidavit. In opposition to this motion, Hendry tries to cure that record through assertions he makes in an affidavit. To the extent Hendry denied expertise during his deposition, he will not be allowed to contradict that denial through this recently submitted affidavit.⁶ Having reviewed the parties' submissions, Takeda's motion to strike is

⁶Mylan also submitted an affidavit from Edwin Bransome in opposition to this motion without disclosing that Bransome has been retained as an expert by Mylan and that he is Hendry's business partner.

granted to the extent that Hendry's affidavit seeks to opine on the

Design, conduct, or interpretation of animal studies

Efficacy or toxicity testing in animals

Strains of rats and mice chosen for study

Calculation of an ED25

Statistical analysis of data from animal experiments

Diabetes

Toxicity

Takeda's intent

Materiality of any data presented to or omitted from the application to the PTO

To the extent Hendry's affidavit seeks to contrast the testing results found in Table I of the '777 patent application with the results he located in Takeda's notebooks, Hendry may present those findings. He may not offer an opinion about the "discrepancies", however, that falls outside the areas of his expertise.

Nusbaum and Stoner

Takeda has moved to preclude Nusbaum from testifying. Mylan has cross-moved to exclude or limit the testimony from Takeda expert Stoner. Both affiants are former members of the PTO, Stoner having been Chief Judge of the Board of Patent Appeals and Interferences from 1995 to 2003. Currently, Nusbaum is a practicing patent attorney and Stoner is teaching law. Neither affiant has any expertise in the scientific areas important to this litigation or in the prosecution of a patent for a pharmaceutical compound. Nusbaum was recently excluded as an

expert witness in a patent case. Applied Materials, Inc. v. Advanced Semiconductor Materials America, Inc., 1995 WL 261407, at *10 (N.D.Cal. Apr. 25 1995).

If this were a jury trial, it would be important to analyze with care the two affidavits and to strike all inadmissible portions of the testimony. Both are vulnerable to attack, particularly Nusbaum, for presenting legal argument and for inserting opinions on issues beyond the affiant's expertise. Nonetheless, both affidavits also contain a description of patent office practice that is of assistance to the Court. The two affidavits will be received as the direct testimony of the witnesses. To the extent that either affiant veers into the presentation of the law or opines on issues beyond his area of expertise, that testimony shall be disregarded.

Landau

On December 9, 2005, Takeda served a supplemental declaration from Bernard Landau, a Takeda expert on animal studies. Mylan has moved to strike the Landau supplemental declaration as untimely. Landau's supplemental declaration was submitted to rebut the previously undisclosed opinions of Mylan expert Ronis which have now been stricken. Mylan's motion to strike the Landau supplemental declaration is granted.

Conclusion

Takeda's motions in limine are granted in part. Its motion to strike portions of the Ronis affidavit is granted. Its motion to strike passages from the Hendry affidavit is granted to the extent described herein. Mylan shall serve revised affidavits

for Ronis and Hendry that comply with the rulings in this Opinion by Wednesday, January 11, at 5:00 p.m. The parties shall confer regarding the proposed revisions on January 12, and present any continuing disputes to the Court by 5:00 p.m. on that day.

Mylan's motion to strike the the Landau supplemental declaration is granted.

Takeda's motion to preclude Nusbaum and Mylan's cross-motion to strike Stoner are denied.

By Wednesday, January 11, at 5:00 p.m., Mylan shall serve a list of the ways in which it will contend at trial that Takeda committed inequitable conduct. The list must conform to the rulings in this Opinion.

SO ORDERED:

Dated: New York, New York
January 9, 2006

Denise Cote
DENISE COTE
United States District Judge